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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/775,687

02/02/2001

Noel K. Maclaren

BII-001CP

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06/10/2002

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BOSTON, MA 02109

EXAMINER

NOLAN, PATRICK J

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,687

Applicant(s)

Maclaren

Examiner

Patrick J. Nolan

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Part III DETAILED ACTION

1. Claims 1-30 are pending.

Restriction/Election

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-4, drawn to a method of diagnosing an autoimmune disease by detecting CD3, CD69, CD94 and CD161 with antibody, classified in class 435, subclass 7.1.

Group II. Claims 1-5, drawn to a method of diagnosing an autoimmune disease by detecting TCR variable regions, CD69, CD94 and CD161 with antibody, classified in class 435, subclass 7.1.

Group III. Claims 1-5 drawn to a method of diagnosing an autoimmune disease by detecting TCR variable regions, CD3, CD69, CD94 and CD161 with antibody, classified in class 435, subclass 7.1.

Group IV. Claims 1-3 and 6, drawn to a method of diagnosing an autoimmune disease by detecting CD4/CD25+ cells that are CD122 or CD132 negative, classified in class 435, subclass 4.

Group V. Claims 7 and 9 drawn to a method of diagnosing an autoimmune disease by detecting indicator T cells, classified in class 435, subclass 29.

Group VI. Claims 8, 10-11, drawn to a method of diagnosing an autoimmune disease by detecting Th1 cytokines, classified in class 435, subclass 7.1.

Group VII. Claims 8, 10, 12, drawn to a method of diagnosing an autoimmune disease by detecting Th2 cytokines, classified in class 435, subclass 7.1.

Group VIII. Claims 8, 10, 12, drawn to a method of diagnosing an autoimmune disease by detecting Th3 cytokines, classified in class 435, subclass 7.1.

Group IX. Claims 13-19 and 27, drawn to a method of treating autoimmune diseases by administering a bacterium from the genus lactobacillus, classified in class 424 subclass 234.1.

Group X. Claims 13-18, 20-22 and 27, drawn to a method of treating autoimmune diseases by administering LPS from a bacterium, classified in class 424 subclass 234.1.

Group XI. Claims 13-18, 20, 23, 27, drawn to a method of treating autoimmune diseases by administering bacterial cell lysate, classified in class 424 subclass 234.1.

Group XII. Claims 13-18, 20, 24, 27, drawn to a method of treating autoimmune diseases by administering purified or recombinant bacterial antigens, classified in class 424 subclass 234.1.

Group XIII. Claims 13-18, 20, 25 and 27, drawn to a method of treating autoimmune diseases by administering lam, classified in class 424 subclass 234.1.

Group XIV. Claims 13-18, 20, 26-27, drawn to a method of treating autoimmune diseases by administering α -galactosylceramide, classified in class 424 subclass 234.1.

Group XV. Claims 28-30, drawn to a kit with antibody, classified in class 530, 387.1.

Group XVI. Claims 28-30, drawn to a kit with nucleic acid, classified in 536 subclass 23.5.

The inventions are distinct, each from the other because of the following reasons:

3. Groups XV and XVI are unique products. They differ with respect to their physicochemical properties and are therefore patentably distinct.

Groups I-XIV are unique methods. They differ with respect to ingredients and method steps. The detection methods are patentable distinct from each other because detect separate compounds, while the treatment methods are distinct from each other because they treat with different compounds.

Groups I-XIV and XV-XVI are unrelated products and methods and are therefore patentably distinct.

4. Because a search of any of these 16 distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the examiner.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to

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a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor or at least one claim remaining in the application. Any amendment of the inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (h).

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Tuesday through Friday from 9:00 am to 5:30 pm.

9. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.


Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
June 7, 2002